REMARKS

The Office Action mailed February 22, 2008 has been carefully considered. The Office Action was labeled as a Final Office Action, however the finality was premature according to MPEP 706.07(a). The finality is premature when the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement. In this case, none of the claims were amended, so the obviousness-type double patenting rejection of claims 1, 5, 9-11, 13-16, 18, 20, 31, 33 and 36-37, newly rejected as being unpatentable over claim 1 of Ghosal (U.S. Patent No. 6,440,436) makes the finality premature. (Previously, the claims were rejected over claim 8 of U.S. Patent No. 6,440,436). A phone call was made to Supervisory Examiner Fred Krass on May 20, 2008, and it was agreed that the finality was premature. In a subsequent phone call with Examiner Webb (newly handling this case), it was agreed that the Examiner would handle the matter so as to provide for a non-final office action.

35 USC § 103

Claims 1-2, 5-11, 13-22, 24-27, 30-34 and 36-37 were rejected under 35 USC § 103(a) as being unpatentable over Ghosal (U.S. Patent No. 6,362,167) in view of Ghosal (U.S. Patent No. 6,440,436) as evidenced by Pushpangadan et al. (U.S. Publication No. 2003/0185913) and in further view of Boynton et al. (U.S. Patent No. 5,087,623). Applicant traverses the rejection.

Applicant respectfully asserts that the Examiner's argument with respect to Pushpangadan et al. misrepresents what the reference states. The Examiner appears to have used improper hindsight to read into Pushpangadan, that which is taught only in the present application.

In particular, the Examiner stated, on page 4 of the Office Action:

"As evidenced by Pushpangadan et al., herbal health compositions can be used to control blood sugar levels in patients with diabetes (page 2, paragraph [0014]). Pushpangadan et al. also disclose commercial herbal anti-diabetic products containing Shilajit and Phyllanthus emblica (pages 9-10, Table 1). Hyperglycemia is defined as abnormally high concentrations of glucose in the circulating blood especially in patients with diabetes. Thus the extract from the fruit of the *Emblica officinalis* plant and purified shilajit can be used to treat hyperglycemia in patients with diabetes."

Actually, in the cited Pushpangadan disclosure at page 2, paragraph [0014], Pushpangadan et al. are describing their own composition, not any other, when they state that the present invention helps to control the blood sugar level and ameliorate the health of diabetics. Their own herbal composition has no shilajit or *Emblica officinalis* plant or chromium (see ingredients para. [0017-0018]). Thus, the statement at page 2, paragraph [0014] of Pushpangadan has no relevance to the presently claimed invention or to any of the other cited prior art references, since it does not concern shilajit or *Emblica officinalis* plant or chromium.

The Examiner's argument also cited to Pushpangadan et al. at pages 9-10, Table 1 for the disclosure of commercial herbal anti-diabetic products containing Shilajit and *Phyllanthus emblica*. The Table does indeed have a column heading entitled "Commercial herbal antidiabetic products" and in this column is a product called Madhumeh Amrit. This product is disclosed to contain 20 herbal ingredients which, indeed, include Shilajit and *P. emblica*. However, there is no information about what properties any of the 20 herbal ingredients provide. The Examiner simply leaped to the conclusion that "the extract from the fruit of the *P. emblica* plant and purified shilajit can be used to treat hyperglycemia in patients with diabetes" without any evidence from any of the prior art to support that conclusion. Neither Pushpangadan et al. nor any of the other cited prior art references provide any information that *P. emblica* or shilajit have hyperglycemic-lowering properties. (Furthermore, Pushpangadan never made any specific disclosure about the nature of the ingredients in the Madhumeh Amrit product, particularly no disclosure as to whether the shilajit was purified nor what part of the *P. emblica* plant was used). The Examiner thus used improper hindsight because the Examiner took the disclosure of the present application which discloses that compositions containing phenolic antioxidant-chromium complex act to lower hyperglycemia (wherein the antioxidant originated from purified shilajit or *Emblica* fruit) and argued that this knowledge about the hyperglycemia-lowering property came from the prior art. It did not.

Since Pushpangadan et al. did not state what the properties were of the individual ingredients in the Madhumeh Amrit disclosed in Table 1, and did not provide any information about the source of the Madhumeh Amrit, it was not possible to know what function *emblica* or shilajit contributed to the Madhumeh Amrit. However, it is reasonable to assume that the 20

different ingredients were mixed together to provide a panoply of health-promoting properties. Without sufficient disclosure from the references and without supporting evidence, the Examiner leaped to a conclusion that Shilajit and *P. emblica* were included for the purpose of treating hyperglycemia. In actuality, this information came only from the present application. Therefore the Examiner used unfair hindsight to credit the prior art with knowledge disclosed only in the present application.

Stating it another way, the Examiner reached the conclusion that it would have been obvious to a person of skill in the art at the time of the invention to modify the extracts disclosed in Ghosal's '167 patent and '436 patent to contain chromium because "according to Pushpangadan et al. and Boynton et al., both the extracts from *Phyllanthus emblica* fruit and purified shilajit and chromium are used to control high blood serum glucose levels." (Statement from Office Action, page 4 bottom to page 5). As explained above, this conclusion is in error because Pushpangadan et al. never disclosed or suggested that extracts from *Phyllanthus emblica* fruit or purified shilajit are useful to control high blood serum glucose levels. Boynton et al. had no disclosure about *P. emblica* or shilajit; the reference is directed to chromium picolinate.

Significantly, Pushpangadan et al. criticized the herbal antidiabetic compositions in Table 1 that the Examiner has relied upon for support. Specifically, Pushpangadan et al. teaches the following:

> "Most of the products (a list given in Table 1) are a mixture of herbs/medicinal plants, minerals, and bhasams (ashes) *without a suitable balanced nutritional composition to ameliorate the general health of diabetics and none of them is a nutraceutical.*" Pushpangadan finishes by teaching: "To the best of the Applicant's knowledge no nutraceutical comprising a combination of legumes, cereals, pseudocereals fortified with herbs/medicinal plants used in the present invention or a process for the preparation of the same exist for diabetic patients."
>
> (Emphasis added)(See page 2, para. [0007]).

The law is clear that skepticism of experts constitutes objective criteria showing nonobviousness and that these objective indicia may often be the most probative and cogent evidence of nonobviousness in the record. *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2d 1196,1202 (Fed. Cir. 2008). The law is also clear that secondary considerations of nonobviousness must be considered in weighing whether the claimed invention is obvious or not. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ at 467; MPEP 2145 ("Office personnel should consider all rebuttal arguments and evidence presented by

applicants.") *In re Piasecki,* 745 F.2d 1468, 1472, 223 USPQ 785, 788 ("[Rebuttal evidence] may relate to any of the *Graham* factors including the so-called secondary considerations."). MPEP 2145. To this end, Pushpangadan's criticism about the ineffectiveness of the very herbal product which the Examiner relied upon, strongly argues against the Examiner's logic and for the nonobviousness of the claimed compositions. Pushpangadan criticizes the Madhumeh Amrit as not ameliorating the health of diabetics (which would mean not correcting hyperglycemia). However, the Examiner failed to take this argument (presented on p. 7 of the last Amendment) into account. This was error.

Even further, Applicant's rebuttal argument in the last Amendment provided for other secondary indicia of nonobviousness, however the Examiner failed to take these indicia into consideration. This was error since "Office personnel should consider all rebuttal arguments and evidence presented by applicants." MPEP 2145. In re *Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (error not to consider evidence presented in the specification).

In the last Amendment Applicant presented the following evidence of secondary indicia of nonobviousness from the specification. Secondary evidence of non-obviousness under *Graham v. John Deere*, includes a showing of long felt but unsolved need. In the present case, although prior art showed that chromium (III) can be used to control high blood serum glucose levels, the problem that was not solved by the prior art was that chromium (III) as a dietary supplement, is converted to toxic chromium (VI) by spontaneous systematic oxidation and hence induces delayed toxicity. (See Specification, Description of Prior Art at page 5, first paragraph). Thus, studies of chromium (III) picolinate and niacin-bound chromium (III), two popular dietary supplements, revealed that chromium (III) picolinate produces significant oxidative stress and DNA damage. (See Specification, page 5, second paragraph). In response to this need, an object of the claimed invention was to provide a composition for treating diabetes or glucose intolerance by employing a safe and effective phenolic antioxidant-chromium complex, without pro-oxidation activity. To this effect, the inventor discovered a particular antioxidant–ligand for chromium that prevents the chromium from being systemically converted from Chromium (III) to Chromium (VI). Thus the claimed invention is for a composition that comprises a phenolic antioxidant, that has no pro-oxidation activity, complexed with chromium. The inventor found

that the phenolic antioxidant that is obtained from shilajit or from *Phyllanthus emblica* or certain other plants provides the safe phenolic antioxidant complex that avoids the conversion of chromium (III) to chromium (VI). This is because the phenolic antioxidants are capable of occupying all the available coordination sites in chromium, thereby eliminating the possibility of forming an undesirable oxo-chromium complex. (See specification at page 10, under the heading "Phenolic Antioxidant(s)"). Thus, there was a long felt but unsolved need that is solved with this invention. The Examiner's failure to consider this secondary consideration of obviousness was error.

Furthermore, it is accepted law that when the invention is more than the predictable use of prior art elements according to their established function, the invention is not obvious. More particularly, the Supreme Court has reiterated that the fact that the individually known elements work together in an unexpected and fruitful manner support the conclusion of non-obviousness. (*KSR International Co. v Teleflex Inc.*, No. 04-1350 (550 U.S.__), (April 30, 2007)). The erroneous conclusion of obviousness, in the present instance is, in one aspect, because the Examiner reviewed the claimed invention as merely a predictable combination of elements to control high blood serum glucose levels, overlooking the unexpected aspects of the claimed invention, namely that the antioxidant ligand for chromium chosen in this invention is capable of occupying all the available coodination sites in chromium, thereby eliminating the possibility of forming undesirable oxo-chromium complex (chromium VI).

Taking all the arguments presented above, it is clear that the facts in this case have significant similarity to the facts in the case of *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2d 1196,1202 (Fed. Cir. 2008). There, as here, the record shows unexpected results as well as skepticism of experts. In *Ortho*, the court found that challenges of the inventive process would have prevented the person of ordinary skill in the art from easily producing the claimed invention in light of the evidence available at the time of the invention. The same should be found in this instance.

With regard to the Examiner's grounds for rejecting specific dependent claims, Applicant asserts the following. Regarding the particular ranges of chromium in the composition (Off. Act. at p.5), in claims 7 and 26, Boynton et al. teach a percentage outside of the range for these

claims. Boynton's 12.5% is clearly higher than the ranges of .02 to 10% and 1 to 8%, respectively for those claims. The Examiner found the prior art to be close enough, and relied on *In re Aller* for the premise that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. However, the facts in this case do not fit those of *In re Aller*. Namely, as stated above, the prior art did not disclose the general conditions of the claims. The prior art showed no evidence that purified shilajit or *emblica* treat hyperglycemia, as the Examiner has erroneously stated. The Examiner's conclusion of obviousness was based on a misread of prior art. As to claims 9, 19 and 27 (Off. Act. at p.5), the Examiner mistakenly based this rejection on an argument as to amount of chromium content in the complex, but these claims are not directed to amount of chromium in the complex. Furthermore, the Examiner made the argument that Ghosal teaches fulvic acids with MW 700-2000. This is irrelevant, since the claims are not directed to fulvic acids with MW 700-2000. Claims 9, 19 and 27 recite hydrolyzable tannins of MW below 1000 or below 2,000. Fulvic acids are not the same as hydrolyzable tannins. Therefore the rejection of these claims is in error.

For all the reasons discussed above, Applicant asserts that the claims are patentable over the cited prior art and respectfully requests that the rejections be reconsidered and withdrawn.

Obviousness-Type Double Patenting

Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33 and 36-37 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 1 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612). This is a new rejection since the previous double patenting rejection used claim 8 of the '436 patent.

Without acquiescing to the correctness of this rejection, in order to advance prosecution, Applicant will file a Terminal Disclaimer at such time as agreement is reached that the claims are otherwise in condition for allowance, if at that time, the form of the claims has not been appreciably amended so as to remove the claims from the obviousness-type double patenting rejection.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

Dated: May 22, 2008

Cynthia Soumoff
Reg. No. 38,314
Attorney for Applicant

MATHEWS, SHEPHERD, McKAY & BRUNEAU, P.A.
29 Thanet Road, Suite 201
Princeton, NJ 08540
Tel: 609 924 8555
Fax: 609 924 3036